James R. Condo (#005867)
Amanda C. Sheridan (#027360)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren, Suite 1900
Phoenix, AZ 85004-2204
Telephone: (602) 382-6000
jcondo@swlaw.com
asheridan@swlaw.com

Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
Matthew B. Lerner (admitted *pro hac vice*)
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH LLP
Atlantic Station
201 17th Street, NW, Suite 1700
Atlanta, GA 30363
Telephone: (404) 322-6000
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS C. R. BARD, INC.'S AND BARD PERIPHERAL VASCULAR, INC.'S MOTION TO EXCLUDE THE OPINIONS OF THOMAS KINNEY, M.D., ANNE CHRISTINE ROBERTS, M.D., AND SANJEEVA KALVA, M.D. AND MEMORANDUM OF LAW IN SUPPORT

(Assigned to the Honorable David G. Campbell)

(Oral Argument Requested)

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

MOTION

Pursuant to Federal Rules of Evidence 702 and 703, and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") respectfully move this Court to exclude portions of the opinions of Plaintiffs' expert witnesses, Thomas Kinney, M.D., Anne Christine Roberts, M.D., and Sanjeeva Kalva, M.D.

MEMORANDUM OF POINTS AND AUTHORITIES

Drs. Thomas Kinney, Anne Christine Roberts, and Sanjeeva Kalva are practicing interventional radiologists, members of radiological societies, reviewers for radiological journals, and authors of articles and presentations concerning the clinical use of IVC filters. While they are certainly qualified to offer opinions about their experience with IVC filters and the medical literature concerning IVC filters, they offer sweeping opinions about many other issues, which should be excluded on the following grounds:

- *Improper Basis, Unreliable*: Drs. Kinney, Roberts, and Kalva rely on the Rule 26 Reports of Drs. Kessler, Ritchie, and Betensky in forming their opinions, which is improper under Rule 703, and their resulting opinions are also unreliable under Rule 702 because they did nothing to independently verify the other experts' opinions.
- *Unhelpful Opinions*: Drs. Kinney, Roberts, and Kalva offer summaries and editorials concerning deposition testimony and less than 0.0028% of the internal Bard documents produced in the litigation. For the most part, this material was selectively identified by the plaintiffs' attorneys, all of which is unhelpful to the jury.
- *Personal Opinions*: Drs. Kinney, Roberts, and Kalva opine about the "reasonable expectations" of physicians and how a "reasonable physician" would think about and act on information. These opinions are inadmissible because they are not grounded in any reliable sources of authority, they have not been tested or peer reviewed, they have no known rate of error, they

have not been published, and the physicians have not identified their view as generally accepted in the medical community.

- *Unqualified Opinions*: Drs. Kinney, Roberts, and Kalva are practicing interventional radiologists with insufficient education, training, and experience to offer opinions about IVC filter engineering and the suitability of Bard's bench testing of its IVC filters.

Accordingly, the Court should limit the opinions of Drs. Kinney, Roberts, and Kalva to their experience with IVC filters and their interpretation of the medical literature.

I. Argument and Citation of Authority

A. *Improper Basis, Unreliable*: Drs. Kinney, Roberts, and Kalva's reliance on the Rule 26 Reports of Drs. Kessler, Ritchie, and Betensky is an improper basis for their opinions under Rule 703 and their resulting opinions are unreliable under Rule 702 because they did nothing to independently verify the other experts' opinions.

Federal Rule of Evidence 703 limits the proper bases of experts' opinions to material that "experts in the particular field would reasonably rely on . . . in forming an opinion on the subject . . . ." Drs. Kinney, Roberts, and Kalva are practicing interventional radiologists who have also published and presented on IVC filters. (Curriculum Vitae ("C.V.") of Dr. Kinney, attached as Exhibit A; C.V. of Dr. Roberts, attached as Exhibit B; C.V. of Dr. Kalva, attached as Exhibit C.) In the physicians' publications and presentations about IVC filters, none appear to cite to opinions generated for litigation, such as those of Drs. Kessler, Ritchie, and Betensky. (*See, e.g.*, Dr. Roberts Dep. Tr., 112:17 to 113:13; 116:16 to 117:5, July 7, 2017 (acknowledging that in her roughly 850 publications and presentations to the medical community, she has not cited opinions generated for litigation), attached as Exhibit D.) Moreover, none of these physicians have ever been shown internal documents and analysis from a medical device manufacturer during the course of their practice, and therefore they have never relied on such documents or analysis during the course of their careers. (Dr. Kinney Dep. Tr., 84:4-8, June 17, 2017, attached as Exhibit E; Ex. D, Roberts Dep. Tr., 225:15-19; Dr. Kalva Dep. Tr., 28:18-25, July 11, 2017, attached as Exhibit F.) Rather, in their publications and

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

presentations, Drs. Kinney, Roberts, and Kalva have cited to the peer-reviewed medical literature and their own experience. (*See, e.g., id.* at 117:7-13 ("When I'm doing a peer-reviewed article, yes, I would generally cite the peer-reviewed literature and usually my own experience.").)

But a significant portion of their Rule 26 Report consists of excerpts and summaries of the reports of Drs. Kessler, Ritchie, and Betensky, which themselves are summaries and commentary on Bard's internal documents. (*See, e.g.*, Rule 26 Rep. of Drs. Kinney, Roberts, and Kalva ¶¶ 62-63, 65-68, 102, 113, 116, 124, 129, 131, 137, 144, 147 (quoting or summarizing Dr. Kessler's Report); 99, 127-28, 132, 134, 164 (quoting or summarizing Dr. Ritchie's Report); 181, 251 (quoting or summarizing Dr. Betensky's Report), attached as Exhibit G.) Dr. Kinney, who was the primary author of all but the final section of the Rule 26 Report, repeated throughout his deposition that his main source for writing the report was Dr. Kessler's report: "The main source for my document was the Kessler report" (Ex. E, Kinney Dep. Tr., 21:5-10); "We basically used the Kessler report" (*id.* at 73:23 to 75:19); "My section, I wrote looking at the Kessler report" and "basically, I went through the Kessler report, and went through sequentially all the different aspects of that" (*id.* at 76:3 to 77:25); "My main focus was the Kessler report" (*id.* at 96:13-18). Dr. Kalva, who was the primary author for the final section of the Rule 26 Report, echoed Dr. Kinney's testimony: "David Kessler's report that we read and heavily relied on." (Ex. F, Kalva Dep. Tr., at 8:24-25.)

Because in their private practice Drs. Kinney, Roberts, and Kalva have never relied on, or cited to, opinions formed for litigation, or any internal company documents or analyses, their opinions derived from the reports of Drs. Kessler, Ritchie, and Betensky should be excluded under Rule 703. *See, e.g., In re Imperial Credit Indust., Inc. Securities Litig.*, 252 F. Supp. 2d 1005, 1013 (C.D. Cal. 2003) (excluding opinions under Rule 703 when "Defendants presented evidence which was essentially unrebutted that it is unprecedented for an auditor to rely upon excerpts from an opinion given in adversarial litigation as a basis for reaching an audit opinion concerning a company's financial

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201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

statements and that excerpts from such an opinion are not of a type reasonably relied upon by accountants in forming audit opinions.").[1]

Aside from violating Rule 703, "an expert's sole or primary reliance on the opinions of other experts raises serious reliability questions" under Rule 702, *In re ConAgra Foods, Inc.*, 302 F.R.D. 537, 556 (C.D. Cal. 2014), and particularly when the "other experts" formed their opinions "for the purpose of litigation," which is precisely what Drs. Kessler, Ritchie, and Betensky did in this case. *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prod. Liab. Litig.*, 978 F. Supp. 2d 1053, 1066 (C.D. Cal. 2013). Admissibility of the expert's opinions in such circumstances requires the expert to have independently verified the underlying expert's work. *See Crescenta Valley Water Dist. v. Exxon Mobile Corp*., No. CV 07-2630-JST (ANX), 2013 WL 12120533, at *5 (C.D. Cal. Mar. 14, 2013) (noting that an expert may rely on the opinions of another expert only after "an independent evaluation of [the other expert's] evidence and methodology") (citation omitted); *Fosmire v. Progressive Max Ins. Co*., 277 F.R.D. 625, 629 (W.D. Wash. 2011) ("Dr. Polissar's expert report is deficient in several ways. First, although his opinions are based on Dr. Siskin's data and methodology, there is nothing in the record to indicate that Dr. Polissar has tested Dr. Siskin's underlying data to ensure its reliability or that Dr. Polissar even has access to Dr. Siskin's underlying data."). Here, however, Drs. Kinney, Roberts, and Kalva undertook

[1] Appendix C to the Rule 26 Report of Drs. Kinney, Roberts, and Kalva contains 100 pages worth of "Schedules" that summarize medical literature, that contain cut and pasted deposition testimony grouped by theme, and that identify by bates number internal Bard documents that allegedly demonstrate "improper use of SIR *Quality Improvement Guidelines*." The Schedules were prepared by the plaintiffs' lawyers, and the doctors did not rely on the Schedules in forming their opinions. (Ex. F, Kalva Dep. Tr., 52:6 to 54:17; 55:8-18; 56:25 to 58:22 (testifying that the Schedules were prepared by the lawyers); Ex. E, Kinney Dep. Tr., 104:13-23; 105:2-15; 105:20 to 106:25; 107:18-25 (testifying that he did not prepare the Schedules, that he does not know who did, and that he did not rely on them in forming his opinions); Ex. D, Roberts Dep. Tr., 139:8-25; 140:15-24; 142:2-9; 142:21 to 143:9; 145:13-16 (same).) Because the doctors did not prepare or rely on these Schedules in forming their opinions, they should be precluded from using them in offering opinions at trial. Nor are the Schedules a proper basis for opinions because the experts do not reasonably rely on lawyer-written summaries of medical literature, deposition testimony, and internal medical device company documents in reaching opinions in the course of their medical practice about IVC filters.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

no effort to independently verify the work of Drs. Kessler, Ritchie, and Betensky. Rather, in drafting the first 105 pages of the Rule 26 Report, Dr. Kinney did not even review the 42 internal Bard documents (0.0028% of the more than 1.5 million documents produced in the litigation) identified on the "Facts and Data Considered" list (let alone the several hundred documents cited in Dr. Kessler's report (which is still less than 0.05% of the documents produced in the litigation)) because "I felt so comfortable with what [Kessler] wrote, that I didn't read all those, no." (Ex. E, Kinney Dep. Tr., 81:22 to 82:7.) Drs. Kinney, Roberts, and Kalva did not review the deposition transcripts of Drs. Kessler, Ritchie, or Betensky (*id.* at 221:7-15); they did not review the underlying data considered by Drs. Kessler, Ritchie, or Betensky (*id.* at 223:9-18); they never spoke to Drs. Kessler, Ritchie, or Betensky (*id.* at 223:20-22); they did not independently verify the methodologies of Drs. Kessler, Ritchie, or Betensky, but rather assumed that the opinions were based on reliable methodologies (*id.* at 225:16-25); and they assumed that Drs. Kessler, Ritchie, and Betensky used reliable underlying data (*id.* at 226:1-5).

Instead of independently verifying the opinions of these other experts, Drs. Kinney, Roberts, and Kalva simply parrot the opinions, say that the opinions are concerning, that the "reasonable expectations" of physicians would be to receive this information, and/or that a "reasonable physician" would have stopped using Bard's filters if they had this information. *See*, for example, among the many such instances, Ex. G, Drs. Kinney, Roberts, and Kalva Rule 26 Rep. ¶¶ 63 ("We fully endorse Dr. David Kessler's opinion that" followed by a two-page quote from Dr. Kessler's report); 65 ("We also endorse Dr. David Kessler's opinions that:" followed by a page and a half quote from Dr. Kessler's report); 102 ("As discussed, below, and in greater detail in the expert report of Dr. David Kessler" followed by a summary of the contents of Dr. Kessler's report); 181 ("The February 2017 Expert report of Dr. Rebecca Betensky as relates to her analyses of Eclipse complaint/AE data states:" followed by an extensive quote from Dr. Betensky's report). This is precisely the kind of testimony that courts in the Ninth Circuit exclude as unreliable. *See, e.g., Cholakyan v. Mercedes-Benz, USA, LCC*, 281 F.R.D. 534 (C.D. Cal.

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201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

2012) (excluding one expert's opinions as unreliable when his Rule 26 report contained large sections taken from a second expert's report, despite the expert having considered numerous other documents to support his opinions). Accordingly, the Court should exclude the opinions of Drs. Kinney, Roberts, and Kalva that are drawn from the reports of Drs. Kessler, Ritchie, and Betensky.

B. *Unhelpful Opinions*: Drs. Kinney, Roberts, and Kalva's summaries and personal editorials concerning deposition testimony and less than 0.0028% of the internal Bard documents produced in the litigation are unhelpful to the jury.

A significant portion of the reports of Drs. Kinney, Roberts, and Kalva amounts to quoting, summarizing, and offering editorials about deposition testimony and Bard's internal documents. (*See, e.g.*, Ex. G, Rep. ¶¶ 80 (summarizing internal technical report), 93 (summarizing and commenting on internal memorandum), 97-98 (summarizing and commenting on deposition testimony), 99 (parroting Dr. Ritchie's report, which itself summarizes internal testing documents), 103-05 (summarizing and commenting on deposition testimony), 107.f.i.-ii. (quoting internal documents), 113-14 (quoting and excerpting internal document), 116 (parroting Dr. Kessler's report, which itself summarizes internal testing documents), 122 (summarizing internal testing documents), 260-78 (summarizing, quoting, and editorializing about internal Bard e-mail and memoranda).)[2] For example, in paragraphs 277 and 278, Drs. Kinney, Roberts, and Kalva quote (and alter with bolding and underlining) an internal e-mail that says nothing substantive about IVC filters, but the doctors nevertheless opine, "There are many, many disconcerting issues with this e-mail. . . . This is disgraceful conduct and provides distressing accolades."

Moreover, the actual number of documents that Drs. Kinney, Roberts, and Kalva

[2] Although prepared by the plaintiffs' lawyers, and not Drs. Kinney, Roberts, and Kalva, Bard's argument applies with equal force to the Schedules appended to the Rule 26 Report, as the Schedules reflect cut and pasted deposition testimony arranged thematically and citations to internal documents that allegedly reflect Bard's "improper use of SIR *Quality Improvement Guidelines*." (Ex. G, Rule 26 Rep. at App. C.)

cite is infinitesimal (42 of more than 1.5 million documents produced, which is less than 0.0028% of the documents in this litigation). And the documents, deposition testimony, and editorializing are arranged to tell the plaintiffs' story in this litigation. Indeed, Dr. Kinney, who was the primary author of all but the last 10 pages of the 114-page report, admitted that the report is making an argument for the plaintiffs' position in this litigation. (Ex. E, Kinney Dep. Tr., 67:15 to 68:11; *see also id.* at 82:21 to 83:6 (describing how he used documents cited in Dr. Kessler's report that were "important to me in my argument").)

Finally, factual narrative and comments about Bard's internal documents and deposition testimony amount to nothing more than plaintiff-slanted summaries of lay matters that courts routinely exclude as unhelpful to the jury.[3] Accordingly, the Court

[3] *See, e.g., Payne v. C. R. Bard, Inc.*, No. 6:11-cv-1582-Orl-37GJK, 2014 WL 988754, at **5-8 (M.D. Fla. Mar. 12, 2014) (rejecting "unhelpful, plaintiff-slanted summaries and characterizations of the evidence which should be excluded as unhelpful to the jury") (citing cases); *Ocasio v. C. R. Bard, Inc.*, No. 8:13-cv-1962-T-36AEP, 2015 WL 2062611, at *4 (M.D. Fla. May 4, 2015) (excluding expert "opinion" that summarized internal company documents because "the jury may consider only the underlying evidence itself, which should be presented directly to the jury through percipient witnesses and exhibits"); *see also, e.g., Andrews v. Metro N. Commuter R.R. Co.*, 882 F.2d 705, 708 (2d Cir. 1989) (finding that narratives of company documents are "lay matters which a jury is capable of understanding and deciding without the expert's help," and citing additional cases in support); *Baldonado v. Wyeth*, No. 04 C 4312, 2012 WL 1802066, at *4 (N.D. Ill. May 17, 2012) (excluding experts' narrative testimony because the vast majority of the "proffered narratives amount to a summary and statement of the experts' advocacy-based interpretation of documents in the record"); *In re: Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1346 (S.D. Fla. 2010), (excluding testimony concerning regulatory history, FDA correspondence, and internal company documents, noting that the issues should be presented to the jury directly, not through an expert who "regurgitates them and reaches conclusory opinions . . . and invades the province of the jury"); *In re: Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (excluding portions of an expert's report because it "presents a narrative of select regulatory events through the summary or selective quotation from internal Merck documents, regulatory findings, and the deposition testimony of Merck employees"); *In re FEMA Trailer Formaldehyde Prods. Liab. Litig.*, MDL 07-1873, 2009 WL 2169224 (E.D. La. July 15, 2009) (excluding expert testimony merely opining as to the facts of the case because the expert's role was more akin to "the role of an 'über-juror' rather than as an expert [with opinions based on specialized knowledge]"); *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 880 (E.D. Ark. 2008) (granting post-trial motion to strike opinion testimony that was merely a summary of internal company documents, as any layperson could have done), aff'd in relevant part, 586 F.3d 547, 571 (8th Cir. 2009); *In re: Baycol Prods. Litig.*, 495 F. Supp. 2d 977, 1014-15 (D. Minn. 2007) (excluding testimony as "lay matters" and "conclusory statements about questions of fact masquerading behind a veneer of technical language" where plaintiffs proffered an expert to opine that Bayer ignored its toxicologists' concerns about Baycol's steep dose-response curve as it concerned Baycol's safety profile); *In re:*

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201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

should preclude Drs. Kinney, Roberts, and Kalva from summarizing and editorializing deposition testimony and Bard's internal documents.

C. *Personal Opinions*: Opinions of Drs. Kinney, Roberts, and Kalva about the "reasonable expectations" of physicians and how a "reasonable physician" would think about and act on information are inadmissible because they are not grounded in any reliable sources of authority, they have not been tested or peer reviewed, they have no known rate of error, they have not been published, and the physicians have not identified their view as generally accepted in the medical community.

Throughout their Rule 26 Report, Drs. Kinney, Roberts, and Kalva opine about the "reasonable expectations of physicians who order the implantation of IVC filters and/or who implant IVC filters." (Ex. G, Rep. ¶¶ 1, 281.) Their opinions include "physicians' reasonable expectations of the requisite pre-clinical and clinical safety and effectiveness/risk-benefit evidence that is mandatory to justify widespread marketing of IVC filters for both temporary and permanent placement" (*id.* ¶ 3.b.); that physicians and patients want "complete, honest and accurate, and frequently updated communications of any and all safety and effectiveness data and information the companies possess and to allow physicians to properly and completely fulfill their obligations of informed consent" (*id.* ¶¶ 7, 65, 66, 76); that physicians have the reasonable expectation that Bard would have provided "details, facts and statistical analyses set forth within Bard's internal documentation" (*id.* ¶ 182); and if physicians had been provided this information, "reasonable physicians would not have used these devices [Bard's Recovery and G2 Filters]" (*id.* ¶¶ 73, 75, 182). In short, these opinions purport to tell the jury what physicians around the country think.

Drs. Kinney, Roberts, and Kalva, however, cite no methodology or scientific principle to support their opinions. When asked how the authors defined the "reasonable expectations" of physicians, Dr. Roberts testified, "I suspect that reasonable is in the eye

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Rezulin Prods. Liab. Litig., 309 F. Supp. 2d 531, 551, 555 (S.D.N.Y. 2004) (excluding expert testimony concerning the alleged downplaying of hepatotoxic effects of Rezulin in the published literature based on internal documents, memos, and e-mails, finding that the issues constituted "lay matters" and would amount to arguing from the witness stand, and to the extent that such evidence is admissible, it is "properly presented through percipient witnesses and documentary evidence.").

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

of the beholder," and "I do not have a written documentation of what reasonable expectation would be." (Ex. D, Roberts Dep. Tr., 230:1 to 231:5.) The doctors have not tested their opinions. (*Id.* at 238:16 to 239:25 (acknowledging that their opinions have not been tested, but it "would be an interesting exercise. Maybe someone could do that study . . . . Maybe I'll do the study").) Because their opinions have not been tested, there is no way to know the rate of error associated with the opinions, nor have Drs. Kinney, Roberts, and Kalva identified anything to demonstrate that their opinions have been peer reviewed or are generally accepted in the community of interventional radiologists. *Daubert v. Merrell Dow Pharms Inc.*, 509 U.S. 579, 593-94 (1993) (identifying four factors to assist courts in assessing whether experts' opinions are reliable, which are whether the theory has been tested, whether the theory has been subject of peer review, the potential rate of error, and whether the theory has gained general acceptance in the relevant scientific community).

Thus, Drs. Kinney, Roberts, and Kalva offer no objective bases, standards, or practices by which to measure their opinions about the "reasonable expectations" of physicians and how a "reasonable physician" would think and act if presented with certain information. As such, the opinions are classic *ipse dixit*, inadmissible opinions. *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert"); *In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d 531, 556-57 (S.D.N.Y. 2004) (rejecting the plaintiffs' arguments that their physician expert was "articulating general principles that physicians require accurate information on labels to make informed decisions" because "the clear import" of the opinions is that physicians would not have prescribed the Rezulin if different information had been provided to the medical community, which is speculative and therefore inadmissible); *In re Diet Drugs Prod. Liab. Litig.*, No. MDL 1203, 2001 WL 454586, at *18 (E.D. Pa. Feb. 1, 2001) (excluding an expert's opinion about how physicians would think and act if the company had provided additional adverse event

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201 17th Street NW, Suite 1700
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information); *In re Diet Drugs Prod. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at *12 (E.D. Pa. June 20, 2000) ("The court can easily preclude, from a *Daubert* viewpoint, the rendering of opinions by either of these [physician] witnesses as to a label's compliance with federal regulatory requirements or as to what doctors in general think, because the witnesses are not qualified for that."); *cf. Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1326 (M.D. Fla. 2015) (excluding subjective experts' opinions in the form of conduct being "unethical" because the experts' offered no professional standard for their opinions and "these opinions appear to be simply [the experts'] subjective views . . . and therefore, are due to be excluded as unreliable."); *In re Trasylol Prod. Liab. Litig.*, No. 08-MD-01928, 2010 WL 1489793, at **8-9 (S.D. Fla. Feb. 24, 2010) (finding that expert opinion grounded in "subjective beliefs and personal views" were inadmissible because they were "not based on 'scientific, technical, or other specialized knowledge' as required by Rule 702."); *In re: Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1053, 1058 (D. Minn. 2007) (excluding opinions as speculative when they were not based on reliable methodology or scientific principle); *In re Rezulin*, 309 F. Supp. at 543 (excluding expert opinions concerning purported ethical standards that were based on the "personal, subjective views" of the experts, which opinions, "[a]t their core, …articulate[d] nothing save for the principle that [defendant] should be honest. Even if charitably viewed as a 'standard,' the testimony nevertheless is 'so vague as to be unhelpful to a fact-finder.'").[4]

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[4] Contrary to a medical malpractice case where testimony about a "reasonable physician" in the context of standard of care that is based on objective and verifiable standards and medical practice as it relates to a particular physician and patient, the opinions that Drs. Kinney, Roberts, and Kalva provide about a "reasonable physician" have no objective bases, standards, or practice to be measured with or against; nor are their opinions related to a particular physician and patient. Rather, they are pronouncing what a "reasonable physician" would think and how a "reasonable physician" would act upon review of material the nature of which Drs. Kinney, Roberts, and Kalva have never seen before in their decades of medical practice.

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201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

D. *Unqualified Opinions*: Drs. Kinney, Roberts, and Kalva are practicing interventional radiologists with insufficient education, training, and experience to offer opinions about IVC filter engineering and the suitability of Bard's bench testing of its IVC filters.

For the last 30 years, Dr. Kinney has focused his work on treating patients as an interventional radiologist. (Ex. E, Kinney Dep. Tr., 32:13-16.) In 1979, Dr. Kinney received a master's degree in mechanical engineering before attending medical school. (Ex. A, Kinney C.V., at 1.) After receiving his degree in 1979, he accepted a job with a physician designing angioplasty balloons, vascular clams, and a cardioplagia jacket for use during open heart surgery. (Ex. E, Kinney Dep. Tr., 24:7 to 25:24.) Dr. Kinney thereafter entered medical school in 1983, and he continued to work with the cardioplagia jackets as part of his independent study project while in school. (*Id.* at 28:3-17.) Since graduating from medical school, Dr. Kinney has not done any medical device design work, (*id.* at 31:12-25), and has never designed any bench top testing. (*Id.* at 35:6-9.)

For the last 35 years, Dr. Roberts has dedicated her career to the practice of interventional radiology. (Ex. D, Roberts Dep. Tr., 28:15-28.) Dr. Roberts received a master's degree in history before attending medical school. (Ex. B, Roberts C.V., at 1.) She has no education, training, or experience in the design of IVC filters, nor is she an engineer. (Ex. D, Roberts Dep. Tr., 28:19 to 29:18.) In 1985, Dr. Roberts was involved to a minor degree in a study of the Bird's Nest filter and the "flow dynamics" of liquid as it passed through the filter. (*Id.* at 30:15 to 31:4.) She has no education, training, or experience, however, concerning bench tests that IVC filters must undergo for regulatory compliance. (*Id.* at 31:5-19.)

Dr. Kalva's training and education is in medicine. (Ex. C, Kalva C.V., at 1.) He is not an engineer. (Ex. F, Kalva Dep. Tr., 24:6-14.) Although, Dr. Kalva claims to be presently designing an IVC filter, he has refused to disclose any details about his involvement other than to say that "I am behind the scenes." (*Id.* at 24:19 to 25:1; 29:7 to 30:1.)

Although Drs. Kinney, Roberts, and Kalva are practicing physicians, a large

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portion of their Rule 26 Report is dedicated to opining about the bench testing and design characteristics of Bard's IVC filters. (Ex. G, Rep. ¶¶ 59-61 (opining about migration resistance as determined by inputs to pre-clinical "bench" tests that simulate use of filters before the filters are cleared for use in patients); 115 (opining about how changing of the size of the diameter of the Bard filter impacted the radial force for the hook to engage the cava wall); 120 (opining about pressure gradient bench testing); 127 (opining about fatigue resistance testing); 133, 167-68 (opining about finite element analysis of Bard's filters); 135, 138 (opining about how fracture of filters can impact forces and loads on the filter); 156 (opining about what the changes to the geometry of the Recovery Filter suggest in terms of loading and radial forces); 161-62 (opining about caudal push migration bench testing); 163-64 (opining about corrosion resistance bench testing).)

But none of the physicians, either in their Rule 26 Report or in their depositions, have identified any experience or knowledge that would qualify them to render opinions about the appropriate or required testing that Bard should have undertaken with its IVC filters. As practicing physicians (and, in the cases of Drs. Kinney and Roberts, more than 30 years from when they had involvement in design or testing of IVC filters), Drs. Kinney, Roberts, and Kalva are not sufficiently qualified to opine about such issues. *See, e.g., Walker v. Ethicon, Inc.*, No. 12-cv-1801, 2017 WL 2992301, at *5 (N.D. Ill. June 22, 2017) (finding that a practicing ob-gyn physician was not qualified to offer opinions concerning whether a medical device manufacturer of pelvic organ prolapse device adequately tested the product); *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *15 (S.D. W. Va. Apr. 28, 2015) (same); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 704-05 (S.D. W. Va. 2014) (excluding opinion of a urogynecologist in a surgical vaginal mesh products liability case that the medical device manufacturer's testing of the product was insufficient because the physician had no experience or knowledge on the appropriate testing that a medical device manufacturer should undertake); *Morritt v. Stryker Corp.*, 973 F. Supp. 2d 177, 188 (E.D.N.Y. 2013) (finding that a physician who had significant clinical experience with the medical device at issue went "well beyond the 'reasonable

confines' of his clinical expertise" when offering opinions regarding biomedical engineering and material science, and that therefore the physician was not qualified to offer such opinions); *Steinman v. Spinal Concepts, Inc.*, No. 05-cv-774S, 2011 WL 4442836, at *5 (W.D.N.Y. Sept. 22, 2011) (finding that an orthopedic surgeon was not qualified to offer opinions about the design of the medical device at issue); *Alexander v. Smith & Nephew, P.L.C.*, 98 F. Supp. 2d 1310, 1315-16 (N.D. Okla. 2000) (excluding design-related and other opinions of a physician who had treated thousands of patients with the device at issue, noting that "[t]he simple possession of a medical degree is insufficient to qualify a physician to testify as to the advantages of a spinal fixation device, the medical causation of spine-related ailments, or the mechanical functioning of an orthopedic implantation device"). Accordingly, the Court should exclude their opinions about engineering suitability of Bard's internal testing.

II. Conclusion

The Court should limit the sweeping opinions of Drs. Kinney, Roberts, and Kalva to their proper areas of expertise, and exclude their opinions grounded in the reports of Drs. Kessler, Ritchie, and Betensky; their summaries and editorials about Bard's internal documents; their personal opinions about the "reasonable expectations" of physicians and how a "reasonable physician" would think and act; and their opinions about engineering issues and the suitability of Bard's internal bench testing of its IVC filters that they are not qualified to offer.

RESPECTFULLY SUBMITTED this 24th day of August, 2017.

s/ Matthew B. Lerner
Richard B. North, Jr.
Georgia Bar No. 545599
Matthew B. Lerner
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH, LLP
Atlantic Station
201 17th Street, NW / Suite 1700
Atlanta, GA 30363
PH: (404) 322-6000
FX: (404) 322-6050
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

James R. Condo (#005867)
Amanda Sheridan (#027360)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren
Phoenix, AZ 85004-2204
PH: (602) 382-6000
jcondo@swlaw.com
asheridan@swlaw.com

Attorneys for Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of August 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/ Matthew B. Lerner

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000